Assessing the Impact of Continuous Quality Improvement on Clinical Practice: What It Will Take to Accelerate Progress

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RESEARCH SUGGESTS THAT ONE-FOURTH OF hospital deaths may be preventable. Each year 180,000 people may die, partly as a result of iatrogenic injury: one-third of some hospital procedures may expose patients to risk without improving their health; one-third of drugs prescribed may not be indicated; and one-third of lab tests showing abnormal results may not be followed up by physicians (Dubois and Brook 1988; Leape 1994; Brook et al. 1990). Increased pressure to contain costs in both the private and public sectors has led to concern that the quality and outcomes of care, as reflected in these data, may only worsen. One reaction to the situation has been greater reliance on health care "report cards," such as those developed by the National Committee for Quality Assurance (NCQA), the Foundation for Accountability (FACCT), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The report of the Presidential National Advisory Commission on Quality Protection in Health Care also underscored this concern. In an effort to deal with both quality and cost issues, providers are looking outside the health

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care sector for inspiration and guidance. The approach they have most often, and visibly, adopted is "continuous quality improvement" (CQI) or "total quality management" (TQM).

CQI can be operationally described as a philosophy of continual improvement of the processes associated with providing a good or service that meets or exceeds customer expectations. This is accomplished by involving a broad array of organizational members, who are trained in basic statistical techniques and tools and are empowered to make decisions based on their analysis of the data. CQI differs from traditional quality assurance methods primarily in its emphasis on understanding and improving the underlying work processes and systems in order to add value rather than on correction of individuals' mistakes after the fact. CQI had come to be widely used in other sectors of the American economy and throughout the world (Deming 1986; Juran 1988) before it was introduced into health care by Berwick (1989) and Laffel and Blumenthal (1989), who wrote seminal articles on the topic, and by a report on an early demonstration program that matched a health care organization with a commercial counterpart (Berwick, Godfrey, and Roessner 1990). A national survey of U.S. hospitals in 1993 found that 69 percent had adopted and were beginning to implement some form of CQI program; of these, 75 percent had done so only within the previous two years (Barsness et al. 1993). Most of these applications, however, have been in administrative areas, such as patient scheduling, record keeping, billing, and related management functions (Williamson 1991; Health Care Advisory Board 1992). Only in the past three or four years has there been any systematic application to clinical practice. In this paper, we will examine the evidence on the clinical application of CQI and identify its strengths and limitations. We will also discuss its role within an integrated approach and recommend ways to accelerate its impact on the field.

Assessing the Evidence

We systematically reviewed the literature between 1991 and 1997 through computerized data searches of Medline and Healthstar; we used as key words "continuous quality improvement," "total quality management and healthcare," "clinical quality improvement," and "clinical process management." The computerized searches were supplemented by manual review of all articles appearing between 1991 and 1997 in

the following journals: *Annals of Internal Medicine*; *Health Services Research*; *Journal of the American Medical Association*; *Joint Commission Journal on Quality Improvement*; *Medical Care*; *New England Journal of Medicine*; and *Quality Management in Health Care*. We supplemented these searches with targeted reviews of specialty journals like *Cancer* and *Journal of Emergency Medicine*.

We relied on "best evidence" when examining the literature (Slavin 1995). In this approach, individual studies are critically appraised to determine a subset of noteworthy studies or groups of studies that are then highlighted for more in-depth review. We used three criteria in making our selections:

1. the strength of the research design
2. the quality of the data collected
3. the likely relevance of the findings for improving clinical practice

Because we were studying specific clinical applications of CQI, we did not explore the vast literature on quality of care and general outcomes research (Lohr 1990).

Assessing the impact of CQI on clinical practice and outcomes of care is problematic for several reasons:

1. It is difficult to measure outcomes in a reliable and valid fashion.
2. It is not always possible to rule out alternative explanations for findings because there are relatively few appropriate controls or randomized trials.
3. The cause-and-effect relations for many conditions (particularly medical) are not understood (Eddy 1984; Office of Technology Assessment 1994).
4. Most studies focus on a single site of care.
5. Studies tend to take as their subject a single condition or process that represents only one particular organizational problem, as when success in one area does not translate to other areas.
6. Generic problems arise in measuring organization-wide performance (Hackman and Wageman 1995).

The literature we reviewed embodies most of these challenges.

We examined the clinical application of CQI to three types of quality problems: overuse, underuse, and misuse. Chassin (1991) describes these

as follows: "Overuse is the provision of health services when their risks outweigh the benefits; underuse is the failure to provide health services when their benefits exceed their risks; and misuse occurs when an appropriate health service has been selected but is then poorly provided." The services that tend to be overused are the prescription of tranquilizers and sedatives, carotid endarterectomies, hysterectomies, and upper GI endoscopy. In the underused category are immunizations, anticoagulation therapy, assessment for depression, prenatal care, and mammography. Common examples of misuse are medication errors and complications or injuries to the patient that are caused by the provider.

Single-Site Studies

The single-site studies were reviewed for types of settings and providers, problems addressed, study design, interventions, and results. Two studies were then reviewed in greater detail based on our three selection criteria noted above.

Settings and Problems Addressed. Of forty-two single-site studies reviewed, thirty-four were performed in inpatient/hospital settings and eight were conducted in outpatient settings; none addressed the continuum of care (table 1). Nine of the inpatient studies focused on surgical procedures, fifteen scrutinized medical procedures and processes, four analyzed the emergency department (ED), one evaluated labor and delivery, and one examined stroke rehabilitation.

TABLE 1
Summary of Studies of Clinical Application of Continuous Quality Improvement

Single-site studies (N = 42)	Multi-site studies (N = 13)
Setting	Setting
Inpatient = 34	Inpatient = 10
Outpatient/primary care = 8	Outpatient/primary care = 3
Continuum of care = 0	Continuum of care = 0
Problem addressed	Problem addressed
Misuse = 23	Misuse = 7
Overuse = 13	Overuse = 2
Underuse = 4	Underuse = 3
Both underuse/overuse = 3	

Many studies targeted reducing length of stay as an objective, but these were only included in the analysis if they also explored the maintenance or improvement of quality and reported measures of these outcomes. Of the forty-two studies reviewed, thirteen addressed overuse of services, three looked at underuse, and twenty-three, misuse (three studies were classified as both overuse and misuse).

Although CQI is mainly used in hospital settings, there are several examples of its adoption in ambulatory care clinics in order to achieve certain goals: reducing appointment no-show rates at a youth mental health clinic (Pellegrin, Carek, and Edwards 1995); improving patient satisfaction with visits (Piccirillo 1996); improving provider continuity of care (Kibbe, Bentz, and McLaughlin 1993); improving the quality of Pap smears (Pachclarz et al. 1992; Burkman et al. 1994); improving the follow-up of abnormal Pap smears (Gottlieb, Margolis, and Schoenbaum 1990); improving several daily work processes in a general internal medicine (GIM) clinic (Young, Ward, and McCarthy 1994); and increasing the number of clinical preventive services (Leshan et al. 1997). Studies of hospital CQI interventions have focused on the following topics:

- reducing costs of care, length of stay (LOS), and patient charges without adversely affecting surgical diagnostic outcomes for patients undergoing carotid endarterectomy (Brothers, Robison, and Elliott 1997), CABGs (Barnes, Lawton, and Briggs 1994), bowel surgery (Mohr et al. 1996), total knee or hip arthroplasty (Gregor et al. 1996), and radical prostatectomy (Ullman et al. 1996)
- reducing costs of care, LOS, and patient charges without adversely affecting nonsurgical diagnostic outcomes among low-risk patients with chest pain in the coronary care unit (Ellrodt et al. 1995) and during their rehabilitation as inpatients (Falconer et al. 1993)
- improving the delivery of in-hospital medications and procedures by upgrading delivery of percutaneous transluminal coronary angioplasty for acute myocardial infarction (Caputo et al. 1997), establishing antibiotic practice guidelines (Pestotnik et al. 1996), reducing the number of late inpatient arrivals for CT scans (Juran 1994), establishing better standards for pain management (Caswell et al. 1996), streamlining pharmacy department processes (Kleefield, Churchill, and Laffel 1991; Zimmerman, Smolarek, and

Stevenson 1997), managing nursing home–acquired pneumonia more efficiently (Dempsey 1995), improving triage to thrombolytic interval for acute myocardial infarction (Krall, Reese, and Donahue 1995), and doing more to meet the needs of cancer patients and their families (McCartney et al. 1997)

- improving the coordination of in-hospital care by reducing ED-to-floor admission time (Jackson and Andrew 1996), improving communication among interdisciplinary staff (Shindollar, Castillo, and Buelow 1995), reducing time intervals for ED fast-track patients, and scheduling more time for patient contact with a physician before discharge (Fernandes and Christenson 1995; Fernandes, Price, and Christenson 1997)
- changing the mix of in-hospital services by decreasing the frequency of episiotomies (Reynolds 1995), lowering the rates of cesarean sections (Myers and Gleicher 1988), switching from intravenous to oral medications for pneumonia patients (Weingarten et al. (1996)
- reducing in-hospital complications from peritoneal dialysis (Dillon, Murphy, and Larson 1995), reducing catheter infections (Civetta, Hudson-Civetta, and Ball 1996; Richard-Smith and Buh 1995), and decreasing medication errors (Carey and Teeters 1995)

Types of Providers. The teams were generally multidisciplinary, although physician involvement varied widely. Physicians either initiated the research or took a strong interest in CQI studies on certain topics: reducing LOS and patient charges for carotid endarterectomy (Brothers et al. 1997) and radical prostatectomy (Ullman et al. 1996), reducing episiotomy rates (Reynolds 1995), improving daily work processes in a GIM clinic (Young, Ward, and McCarthy 1994), and increasing provider continuity of care in an ambulatory setting (Kibbe, Bentz, and McLaughlin 1993). Many CQI initiatives were started and directed by nursing personnel (Dillon, Murphy, and Larson 1995; Richard-Smith and Buh 1995; Shindollar, Castillo, and Buelow 1995). One project to improve pharmacy processes—prompted by nurse dissatisfaction—failed to include nonpharmacy personnel on the CQI team (Kleefield, Churchill, and Laffel 1991).

Study Design. Only two of the single-site studies reviewed used a randomized design (Falconer et al. 1993; Pellegrin, Carek, and Edwards 1995). The remaining studies were designed as pre/postobservations.

Chart reviews and administrative databases were primary data sources for CQI studies. Almost all authors noted the limitation imposed by their study designs, which made it impossible to deduce whether the CQI process or other unknown factors were responsible for the results.

Interventions. In line with the philosophy of CQI, each intervention was unique to the problem at hand. However, provider training and education were the most common interventions, either alone (Carey and Teeters 1995; Dillon, Murphy, and Larson 1995; Horne 1996), or in concert with information dissemination (Reynolds 1995), or with other interventions (Burkman et al. 1994; Gregor et al. 1996; Pachclarz et al. 1992; Shindollar, Castillo, and Buelow 1995). Other common interventions were information dissemination, feedback to staff, guideline/protocol development (Barnes, Lawton, and Briggs 1994; Caswell et al. 1996; Dempsey 1995; Gregor et al. 1996; Juran 1994; Krall, Reese, and Donahue 1995; Roman, Linekin, and Stagnaro-Green 1995), physician retraining (Ullman et al. 1996), and feedback from utilization managers or case managers (Ellrodt et al. 1995; Kong, Belman, and Weingarten 1997; Weingarten et al. 1994). One study used a computer-assisted decision support system as part of an antibiotic management program (Pestotnik et al. 1996).

Results. The majority of the studies we examined reported positive findings on the variables of interest. For example, CQI efforts to reduce LOS and patient charges for carotid endarterectomy resulted in statistically significant ($P < .001$) decreases in both LOS and patient charges, with no change in patient mortality (Brothers, Robison, and Elliott 1997). Pestotnik et al. (1996) utilized a systems approach to improving antibiotic management that resulted in fewer adverse drug events, a lower mortality rate, and reduced costs. Gregor et al. (1996) found that implementing a clinical path reduced LOS, decreased inappropriate use of perioperative antibiotics, and diminished the need for laboratory tests without compromising patient outcomes. The studies that focused on reducing the time between arrival in the ER and admission to the floor (Jackson and Andrew 1996) and on compressing the intervals from triage to thrombolytic administration and triage to ECG (Krall, Reese, and Donahue 1995) also achieved positive, significant results.

Notably, the two studies that relied on randomized clinical trials did not show any changes (Falconer et al. 1993; Pellegrin, Carek, and Edwards 1995). Nor were studies that used case managers or utilization managers for the care of chronic obstructive pulmonary disease (COPD)

(Kong, Belman, and Weingarten 1997) and congestive heart failure (Weingarten et al. 1994) associated with any improvement.

Selected CQI Studies

The types of clinical applications are illustrated by two studies:

Implementing Antibiotic Practice Guidelines through Computer-Assisted Decision Support: Clinical and Financial Outcomes. Pestotnik et al. (1996) present a descriptive epidemiological study and financial analysis project that transformed antibiotic practice guidelines by linking clinical and financial outcomes. The results were achieved with the support of computer-assisted decision making. The researchers' working hypothesis was that a systems approach that combined practice guidelines and comprehensive information systems could improve the quality of care. All 162,196 patients discharged between January 1, 1988, and December 31, 1994, from a large community teaching hospital in Salt Lake City were screened for antibiotic use. The intervention was an antibiotic management program that used local, clinician-derived consensus guidelines embedded in computer-assisted decision support programs. Measures included antibiotic use, clinical outcomes, and financial outcomes. During the study period, 39.3 percent of hospitalized patients received antibiotics. Although the proportion of patients who received antibiotics increased each year (from 31.8 percent to 53.1 percent), total antibiotic use decreased by 22.8 percent. The percentage of patients who received appropriately timed preoperative antibiotics increased from 40 percent to 99.1 percent. Antibiotic-associated adverse drug events decreased by 30 percent, antimicrobial resistance patterns and LOS were stable, and mortality rates for patients treated with antibiotics decreased significantly (3.65 percent to 2.65 percent; $P < .001$). Inflation-adjusted total acquisition costs of antibiotics and antibiotic costs per treated patient decreased.

Improving Surgical Care of Prostate Cancer. A single-specialty urology group in Southern California, faced with their first capitated-care contract, led a multidisciplinary effort (of primarily physicians and nurses) to improve the quality and the costs of care for prostate cancer patients (Ullman et al. 1996). A flow chart outlined the steps preoperatively, in hospital, and during recovery for men undergoing a radical prostatectomy, which enabled the project participants to identify the factors associated with delayed recovery: overuse of medical resources, like nar-

cotics and nasogastric tubes, and little encouragement of liquid and oral feeding; expensive operative techniques, like the use of surgical staples; misuse of postoperative resources, like antibiotics (use of expensive agents when less expensive antibiotics would suffice); and autologous blood donation (expensive to collect and rarely used). Staffing of cases was also improved by prospectively identifying difficult cases and then enlisting the help of a second surgeon. Feedback about adverse clinical outcome rates to the individual urologists led to the identification of two physicians whose surgical technique was poor. These physicians, who had both recently completed residency training programs, voluntarily enrolled in a continuing medical education surgical course. Once they had been retrained, the adverse outcome rate dropped to 3 percent (from an earlier figure of 30 percent). Average length of stay decreased from 5.4 days to 4.1 days, while charges decreased from $19,000 to $14,000 and payment received fell from $6,290 to $5,700.

Multisite Studies

Thirteen multisite studies reporting results were identified; of these, three studies are currently in progress. Six studies focused on heart disease (O'Connor et al. 1996a; Krall, Reese, and Donahue 1995; Philbin et al. 1996; Meehan et al. 1996; Mitchell et al. 1996; Gordian and Ballard 1997). Other categories were examined as well: one looked into both hypertension and depression (Horowitz et al. 1996; Goldberg et al. 1998); one, adverse drug events (Leape et al. 1995); one, cystitis (O'Connor et al. 1996b); one, pediatric immunization rates (Carlin, Carlson, and Nordin 1996); and, finally, one took on six conditions: acute myocardial infarction, COPD, congestive heart failure, pneumonia, stroke, and total hip replacement (Shortell et al. 1995b). The studies in progress have as their subjects congestive heart failure (Philbin et al. 1996), CABG surgery, total hip replacement (Shortell et al. 1998), and preventive practices (Solberg et al. 1996). Ten of the completed thirteen multisite studies examined acute hospital care; only three dealt with primary care issues; and none addressed quality issues across the continuum of acute, primary, and follow-up care.

Seven of the completed thirteen studies addressed issues of misuse (i.e., focused on improving care without questioning the amount of care that was provided); four focused on appropriateness of care in terms of

underuse (e.g., pediatric immunization rates, use of a cystitis guideline, use of hypertension and depression guidelines, and increasing the administration of thrombolytic therapy); and two examined overuse (e.g., length of stay). All three studies in progress are primarily concerned with misuse. With regard to study design, only one of the thirteen studies reporting results employed a randomized trial, one used a matched comparison group, and the remaining were before-and-after observational or cross-sectional studies. Of the three studies in progress, two are randomized clinical trials and one is a prospective cohort study. Results from most of the nonrandomized studies suggest significant improvements associated with CQI interventions (e.g., increased immunization rates, shorter intervals between thrombolytic administration times, and lower risk-adjusted death rates), but the one randomized study found no impact. Two of the nonrandomized studies and the one randomized study are highlighted below.

Improving Outcomes of CABG Surgery

Five medical centers in Maine, New Hampshire, and Vermont and twenty-three associated cardiac thoracic surgeons entered into a collaborative arrangement to improve the quality and outcomes of care for CABG patients. Data were collected on 6,638 patients in the three years prior to the intervention in 1990 and on 6,488 patients during the two years following intervention. The intervention period itself covered nine months, from July, 1990, to March, 1991, and was in three parts:

1. feedback of risk-adjusted outcome data, which was distributed three times a year to individual physicians, apprising them of their own results and of the medical center and regional results
2. a two-day training session in CQI techniques for the executive committee members and two four-hour training sessions for everyone else
3. site visits to observe the practices of other medical centers

Despite the fact that patients in the postintervention period were older and more likely to have comorbid conditions, there were 74 (24 percent) fewer deaths during this period than would have been expected (SMR = 0.76 ; CI = 0.67 to 0.90; $P = .001$). Interestingly, there was no reduc-

tion for elective patients; only for urgent/emergent patients. Four of the five medical centers experienced reductions; the fifth had the lowest risk-adjusted mortality rate before the intervention (O'Connor et al. 1996a). All the medical centers are continuing to collaborate in order to improve care for cardiovascular patients and are examining a broader array of patient outcomes.

Improving Pediatric Immunization Rates

Nineteen medical clinics associated with Health Partners in the Twin Cities organized a multidisciplinary CQI team to improve the immunization rates of two-year-old children. The team comprised a pediatrician team leader, other pediatricians, a family practitioner, a pediatrics head nurse, a clinic manager, a clinic systems specialist, and a facilitator. The team used various CQI techniques (flow charts, control charts, cause-and-effect diagrams) to determine the causes of late or missed appointments, which they discovered to be chiefly missed opportunities when the child was in the clinic for another reason, no previous visits or the absence of a chart, and lack of instruction for parents. Based on these findings, certain interventions were implemented: development of algorithms, simplifying the location of medical records, and creating an automated vaccine administration record for two of the clinics. These efforts resulted in an increase in immunizations from 53 percent to 86 percent over a period of four quarters. The authors stressed the importance of providing feedback at the clinical level and to individual physicians, in addition to aggregate results (Carlin, Carlson, and Nordin 1996).

Increasing Compliance with Hypertension and Depression Guidelines

Fifteen small group practices at four Seattle primary care clinics were randomly assigned to three study conditions: academic detailing alone, academic detailing plus continuous quality improvement (CQI) teams, or usual care. Ninety-five providers and 4,995 patients were then tracked over the year to assess changes in hypertension prescribing, blood-pressure control, depression recognition, use of older tricyclics, and scores on the Hopkins Symptom Checklist depression scale. No effects

were found for the CQI teams in any of the sites or for either disease condition. In one site, however, the use of both academic detailing and CQI did increase the percentage of hypertensive patients who were adequately controlled. The authors believe the lack of impact was largely due to the varying ability of the teams to implement CQI processes, suggesting the importance of taking into account differences in organizational culture (Goldberg et al. 1998).

Conclusions

Four conclusions may be drawn from review of the existing literature on the clinical application of CQI. First, the literature is relatively sparse: 42 single-site studies have been identified and only 13 multisite studies. This, of course, is understandable because CQI has been systematically applied to clinical processes and conditions only recently. Second, because the existing studies have largely been before-and-after observations, it is difficult to know whether the reported improvements are due to the CQI interventions or to competing explanations. Third, most studies have addressed issues of misuse; fewer have examined overuse or underuse in current practice. It is difficult to argue that this is an inherent limitation of the CQI approach. More likely, it reflects issues of greatest concern to providers at this time. Fourth, most studies report favorable results. The early evidence suggests that quality and outcomes of care can be improved and certain efficiencies achieved through the application of CQI to clinical conditions and processes. Particularly important correlates of success appear to be the participation of a nucleus of physicians, feedback to individual practitioners, and a supportive organizational culture for maintaining the gains that are achieved. Failures tend to derive from poor choice of condition for CQI application, such as congestive heart failure, COPD, and depression, which pose many difficulties in implementation (Weingarten et al. 1994; Kong, Belman, and Weingarten 1997; Goldberg et al. 1998); nonacceptance by local physicians of national guidelines; poor dissemination (Kosecoff et al. 1987); and vague, diffuse feedback to practitioners. The generally positive findings, however, must be tempered by the relatively weak study designs on which they are based. Further, the denominator of submitted articles on the clinical application of CQI is not known. Because studies showing "no results" are less likely to be published, or perhaps even to be submitted for consideration, the actual impact of

CQI on clinical practice may be overstated. The existing literature does, however, provide a basis for assessment: of some of the strengths and limitations of the CQI approach; of the role it can play within an overall integrated approach to quality improvement; and of the possibilities for its further diffusion across the field.

Strengths and Limitations of the CQI Approach

CQI may be thought of as a beautiful rose growing in an unruly garden filled with weeds. The "unruly garden" is the U.S. health care system, and the "weeds" are well known to everyone: misaligned incentives, professional entrenchments, competing priorities, organizational inertia, and lack of adequate information systems, to note a few. The weaknesses of CQI do not lie so much in the approach itself but, rather, in the infrastructure required for its success. CQI's major weakness, if you will, is that it is *very demanding* of individuals and organizations along multiple dimensions: cognitively, emotionally, physically, and, some might say, spiritually. For the CQI rose to flourish, it must be carefully cultivated in a rich soil bed (e.g., a receptive organization), given constant attention (e.g., sustained leadership), assured of appropriate amounts of light (e.g., training and support) and water (e.g., measurement and data systems), and protected from damaging pests (e.g., overly burdensome regulation and parochial views).

Its strengths may make the "gardening" worth the effort. Most prominent is CQI's fourfold focus:

1. on determining and meeting the needs of patients or customers
2. on a holistic approach to quality improvement, based on identification of underlying causes of poor performance
3. on fact-based management and scientific methodology, which make it culturally compatible with the values of health care professionals
4. on empowering its practitioners to improve quality on a daily basis

However, as we suggested earlier, these are *conceptual* strengths. The extent to which they are realized depends on the ability and willingness of individuals, groups, and organizations to implement them. Blumenthal

and Epstein (1996) note: "Despite its clear success in particular instances, there is so far no convincing evidence that the application of the techniques of total quality management in health care improves the quality of care in entire institutions or among large numbers of physicians."

One approach to the challenge is to consider four interrelated dimensions that are necessary for CQI success: strategic, cultural, technical, and structural (O'Brien et al. 1995). The *strategic* dimension emphasizes the conditions and processes that are strategically most important to the organization and that offer the greatest opportunity for improvement. A primary care group practice may choose to upgrade its prevention practices. An acute care hospital, on the other hand, may select high-cost, high-volume conditions and procedures as its priority. The *cultural* dimension refers to the underlying beliefs, values, norms, and behaviors of the organization that either inhibit or support CQI work. A culture that fosters openness, collaboration, teamwork, and learning from mistakes appears to be optimal (Shortell et al. 1995b). The *technical* dimension refers to the training and information support system issues. Are people sufficiently trained and supported by the necessary data and information systems to succeed in undertaking clinical quality improvement efforts? Finally, the *structural* dimension refers to the presence—or absence—of appropriate mechanisms to facilitate learning and to disseminate the "best practices" throughout the organization. These mechanisms include task forces, committees, quality improvement steering councils, ad hoc work groups, electronic communication, and related methods.

All four dimensions must be present for significant organization-wide improvement to occur. Table 2 illustrates their multiplicative function, indicating that if, for example, the strategic dimension is missing, despite the presence of the other three, the result is likely to be little or no impact on anything really important. This is true because the organization is wasting its energy on peripheral, less strategically important activities and has not stopped to ask,"What are the most important core clinical activities whose improvement will make the biggest difference in our success as an organization?"

The second row of table 2 illustrates a situation in which the cultural dimension is missing, resulting in small, temporary effects of no lasting value. Essentially, no one notices what is happening because the improvement is not acknowledged or supported by the culture. Achievements are not celebrated, nor is celebration woven into the system of performance appraisal and reward. The response to a suggestion for

TABLE 2
Dimensions Needed to Achieve Clinical Quality Improvement Across the Organization[a]

Strategic	×	Cultural	×	Technical	×	Structural	=	Result
0		1		1		1	=	No significant results on anything really important
1		0		1		1	=	Small, temporary effects; no lasting impact
1		1		0		1	=	Frustration and false starts
1		1		1		0	=	Inability to capture the learning and spread it throughout the organization
1		1		1		1	=	Lasting organization-wide impact

[a]0 = absent; 1 = fully present.
Source: Adapted from S.M. Shortell et al. (1996, 159).

doing so might well be, "It is really not how business is done around here." As a result, there are real problems in "holding on to any gains." Backsliding is the order of the day.

In the third row, the missing technical dimension reveals a situation of considerable frustration and false starts. People working on multidisciplinary teams are not sufficiently trained and/or the supporting information and data analysis are inadequate. This is a frequent barrier to clinical quality improvement work because most organizations' clinical information systems are inadequate, a state of affairs that is particularly frustrating to physicians.

The fourth row, in which the structural dimension is missing, results in an inability to capture the learning and spread it throughout the organization, a situation that is prevalent in health care organizations because their activities are highly specialized and the work is highly complex. As a result, they often do not achieve optimal results when they undertake clinical quality improvement projects.

Through extensive research, the obstacles associated with each dimension have been identified (Berwick, Godfrey, and Roessner 1990; Gaucher and Coffey 1993; Joint Commission on Accreditation of Health-

care Organizations 1992; Kaluzny, McLaughlin, and Kibbe 1992; Melum and Sinoris 1993; O'Brien et al. 1994; Sahney and Warden 1991; Shortell et al. 1995b; *Quality Letter* 1993). The *cultural* obstacles (Shortell et al. 1995a) arise when organizations look inward to the needs of their professionals, rather than outward to the needs of their customers, or when physicians do not become involved because of inexperience or resistance to working as members of teams, or because they perceive that CQI is primarily a cost-control mechanism (McLaughlin and Kaluzny 1990). Frequent *technical* obstacles are the lack of team-based, problem-focused training, insufficient provision for ongoing training and upgrading of skills (particularly for quality improvement facilitators), and inadequate or nonexistent information systems. *Strategically*, the main obstacles are an inability to select goals that would clearly fit into the organization's strategic priorities and failure to make quality improvement work a central part of organizational planning. Finally, there are prominent *structural* barriers:

1. Failure to take advantage of organization-wide steering councils or similar groups, which can perform several valuable functions: they can serve as forums for rewards and celebrations; help keep the focus on the strategic goals of the organization; facilitate learning across projects; remove departmental barriers to successful teamwork; and conduct thorough, ongoing evaluations.
2. Lack of alignment between the budgeting and planning systems.

Physician Involvement

The role of physicians in CQI work merits special attention. Many investigators have stressed the importance of early physician involvement and support to successful quality improvement efforts (Blumenthal and Edwards 1995; Conway, Keller, and Wennberg 1995; Horne 1996; Kaluzny, McLaughlin, and Kibbe 1992; Lammers et al. 1996; Maleka and O'Connor 1995; McEachern 1993; Mosser 1996; and Shortell 1995).

Recent research supports the notion that CQI is likely to be more effective if physicians are meaningfully involved in the governance of the organization (Weiner, Alexander, and Shortell 1996). A national study of 2,193 hospitals revealed that when physicians were more in-

volved in governance, more departments adopted CQI projects; quality-of-care data were used for more conditions; and a significantly higher percentage of physicians were trained in CQI and actively participated in CQI teams (Weiner, Shortell, and Alexander 1997).

Conclusion

It is clear that the clinical application of CQI is complex and demanding. Although there are "pockets of improvement," no evidence has yet emerged of an organization-wide impact on quality. Such an achievement will require a comprehensive approach to learning and knowledge building, in which technical skills, clinical expertise, a grasp of continuous improvement principles and practices, and familiarity with organization theory and behavior all play a part (Batalden and Mohr 1997). The overall system of treating and caring for patients must be transformed into a culture that emphasizes integration and teamwork rather than individualism, measurement for improvement rather than judgment, and continuous learning from each other rather than identification of "best practices" that are treated as sacred cows (Berwick 1996). Such systemwide improvement may require special initiatives. One successful example is the Institute of Clinical Systems Integration (ICSI), a Twin Cities–based consortium comprising Health Partners, HealthSystem Minnesota, the Mayo Clinic, and the Buyers Health Care Action Group (BHCAG 1997). ICSI has adopted certain quality principles: a committed leadership; meeting the perceived needs of clinicians and patients; developing a *system* of implementation based on repeatedly used routines; effective staff support at the right time and *pace*; a culture that respects a certain degree of autonomy; and appropriate alignment with compensation systems. In brief, CQI is likely to achieve its greatest potential when it is integrated into a systematic, organization-wide effort.

The Role of CQI within an Integrated Approach

We believe that CQI will achieve its greatest potential if viewed as part of a set of capabilities that organizations need to improve the health of individuals and communities. This is depicted in figure 1 as a "capa-

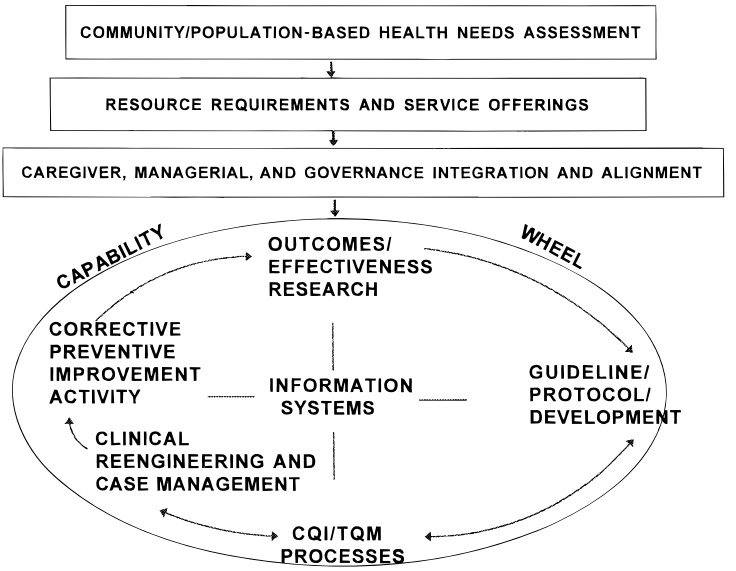

FIG. 1. The community health care management system.

bility wheel." The wheel must be balanced on a three-part frame or foundation: knowledge of the community's health needs; adequate services, personnel, and facilities; and a sense of shared mission that unites providers, executives, and trustees around a common set of objectives; and appropriate incentives. The capability wheel revolves on this framework and contains a set of continuously reinforcing activities:

1. determination of the current state of knowledge about a given condition (e.g., diabetes, asthma, coronary artery disease, domestic violence, head injuries)
2. development of action plans (guidelines, protocols, and pathways) for dealing with the condition
3. application of CQI practices to care of the condition (and, as indicated by the double-headed arrow, to guideline development itself)
4. undertaking clinical re-engineering and general case management as necessary, a task that can be heavily influenced by CQI but that goes beyond improving current procedures to redefining the entire process of care

5. implementing the intervention
6. assessing the outcomes and comparing them against the performance and outcomes of similar organizations

Figure 1 shows how these interrelated processes and activities are anchored by the quality of underlying information systems and their capacity to produce accurate, reliable, and interpretable data. The capability wheel can be applied to appropriateness of care (i.e., overuse and underuse) and to current processes (i.e., misuse).

This work, of course, takes place within the larger political economy of health care delivery that is affected by issues of regulation, competition, a mixed array of financial incentives, and related forces. It is unlikely that the clinical potential of CQI will be realized without the *intentional design* of the regulatory, competitive, and payment forces to promote such work. Some might argue that these factors currently impede CQI work (Chassin 1996). For example, regulation that focuses on means rather than ends and that sets thresholds or "floor" requirements for behavior is antithetical to CQI philosophy and approaches. Some of the legislation pertaining to licensure and certification of professionals serves as an example. Also, despite its good intentions, some patient self-protection legislation may be problematic from a CQI perspective. Payment incentives that reward volume or productivity or cost-cutting efficiencies, without taking into account patient satisfaction or the quality and outcomes of treatment, constitute another counterproductive factor. Finally, competition that is primarily based on price or cost only works against CQI implementation.

Because topics of regulation, payment, and competition are addressed by others in this issue (see the articles by Brennan, Sisk, and Dudley et al.), only a few points will be made here. First, regulation, payment policies, and competition can play important roles in promoting a new "dominant logic" of health care delivery based on *value* through an emphasis on the combination of cost and quality dimensions desired by "consumers." For example, regulators might give greater latitude to individual and systems providers in their use of personnel. In contrast, more regulation may be needed to address underuse issues that cannot be remedied through competitive forces, financial incentives, or even CQI.

From an accreditation perspective, the Joint Commission has recently taken a step in the right direction by deciding to emphasize outcomes

and performance and to move away from requiring specific approaches to quality improvement. On the payment side, rewarding providers based on patient satisfaction and clinical and functional health status outcomes, rather than on cost and productivity criteria alone, is another positive development.

On the competitive dimension, creating a market that rewards value, and not merely the lowest-cost provider, will promote clinical CQI efforts. For example, in the Twin Cities, the BHAG, a consortium of leading public and private sector employers, is purchasing health services directly from "care systems," based on quality as well as price criteria (Buyers Health Care Action Group 1997). In fact, during the first round of negotiations, a care system was not even considered eligible unless it had completed at least one clinical quality improvement project with results. In future negotiations more achievements will be expected.

Accelerating the Impact: The Issue of Diffusion

It is important to distinguish between the external diffusion of CQI throughout the health care field and its internal diffusion within given health care organizations and systems. Various networks and institutes are working energetically on external diffusion. For example, the Institute for Health Care Improvement has been a leader, offering a range of education, demonstration, and technical assistance programs that have been attended by thousands of individuals and organizations. Its recent Breakthrough Series provides opportunities for targeted CQI work in areas like coronary artery disease, diabetes management, and intensive care. For the past several years, David Gustafson and his colleagues at the University of Wisconsin have been building a Quality Improvement Support System (QISS); they have brought together approximately 40 organizations to collaborate on improving processes and outcomes of care, ranging from acute chest pain to cardiac surgery to reducing cesarean section rates to improving outcomes for total hip replacement patients. The Quality Improvement Networks (QINs) of the Health Care Forum and the Northern New England Cardiovascular Care Group also represent valuable collaborative efforts.

What have these initiative taught us? First, there is evidence to suggest that early adopters and implementers of CQI do so primarily to

improve performance, whereas those who come to it later are primarily concerned with achieving external legitimacy—that is, with gaining credibility as CQI becomes "the thing to do" (Westphal, Gulati, and Shortell 1997). Both effects are magnified when a hospital is a member of a health system or network. These results suggest that there is likely to be considerable variation in how CQI is implemented, depending on the motivations of the organization. Also, membership in a system or network promotes greater diffusion, which may result in markedly different effects on clinical outcomes, depending on whether the system or network is an early or late adopter. Experience with diffusion has led to certain caveats:

1. It is very difficult to work across departments and divisions.
2. It is also difficult to work across hospitals within a given system, even when the system hospitals have "adopted" CQI.
3. A very high level of data analysis and interpretation support is needed throughout the process (Gustafson et al. 1997).

Whereas the challenges to external diffusion of the concept throughout the field are formidable, the obstacles to internal diffusion within a given health care organization may be even greater. Many factors can join to block its success: the short-run-crisis orientation of many provider organizations; a preoccupation with reducing costs; inadequate information systems; physician resistance; organizational inertia; and, not least, the larger political economy of health care delivery, which militates against true CQI efforts. These factors are compounded by the inherent complexity and scope of health care delivery itself.

Nonetheless, some progress is being made within selected organizations. Intermountain Health Care (IHC), the Henry Ford Health System, Group Health Cooperative of Puget Sound, and HealthSystem Minnesota represent a few examples. IHC, for example, has 60 ongoing clinical improvement initiatives that are resulting in approximately $30 million of annual savings. These initiatives owe their success to an enormous amount of consistent leadership, hard work, and persistence, and they have all benefited from the existence of "clinical effectiveness and outcomes" support units. As entities, they comprise clinicians, biostatisticians, epidemiologists, data analysts, and information technology experts, who help design studies, collect and analyze data, and assist caregivers with interpretation and application. Supported by these units,

the Institute for Clinical Systems Integration, mentioned above, has developed CQI-driven guidelines for as many as 16 different conditions or procedures, and it is working on many others. In turn, some of these guidelines are being used in randomized clinical trial interventions in order to assess their impact on outcomes (Mosser 1996). More work of this kind is needed. However, unless there is a new political economy of health care delivery and a greater sense of urgency for change based on the value that can be created through CQI-driven clinical process improvement, it is unlikely that either internal or external diffusion will occur on a large scale.

Conclusion and Future Directions

Clinical quality improvement applications are more likely to be effective under certain conditions:

1. When they are carefully focused on areas of real importance to the organization and addressed with clearly formulated interventions.
2. When the organization is ready for change and has prepared itself by appointing capable leadership, creating relationships of trust with physicians, and developing adequate information systems.
3. When there is a conducive external environment relative to beneficial regulatory, payment policy, and competitive factors.

Although there are many barriers to accelerating the clinical application of CQI, there are also some important facilitators. Among these is the recognition that CQI is highly compatible with professional values. It combines the scientific and humanistic values of the health professions in an understandable and coherent fashion. Also, compared with many other fields, health care has a large percentage of highly trained, well-educated professionals who are capable of applying the philosophy and practices of CQI. Further, the enrollment of greater numbers of Medicare and Medicaid beneficiaries in managed care programs will increase the incentives to maintain quality within the cost-containment practices of such programs. This should increase the pressure to provide greater clinical value and thus to apply CQI methods to achieve this value. Also, as private-sector markets mature to the point of health

plans being within dollars and cents of each other on premiums and costs, competition will begin to occur on other dimensions, like service and technical quality, as plans and providers strive to differentiate themselves from each other to win more enrollees. (This may already be taking place in the Twin Cities area.) Finally, as both the public and private sectors and the public at large call for "evidence-based accountability" in the form of report cards and related measures, CQI will be used as part of a comprehensive approach to providing such accountability.

Figure 2 lists three major factors that will influence the likely demand for clinical applications of CQI, four factors that will facilitate its wider use, and three ways that it will be put to use. In addition, three major, but neglected, areas of need are listed: The first is incorporation of CQI philosophy, techniques, and approaches into the curricula of the health professional schools—for example, into medicine, nursing, public health, pharmacy, dentistry, social work, and health services management—and into the continuing education of health professionals. A few projects have been launched (Batalden and Mohr 1997; Batalden 1998; Baker et al. 1998; McLaughlin and Kaluzny 1995; Gelmon and Baker 1995; Headrick, Neuhauser, and Melnikow 1993). CQI skills and expertise can be viewed as the "yeast" that transforms technical skills into optimal patient care.

Second, although a great deal of work remains to be done in the application of CQI to traditional, "numerator based" diseases and conditions, its application to population-based, "denominator" medicine requires attention (Brook, Kamberg, and McGlynn 1996). Issues like bicycle-caused head injuries, teenage pregnancies, vaccine-preventable childhood diseases, domestic violence, substance abuse, lead poisoning, and related community health problems are also "clinical problems." They call for different approaches than those found within traditional, acute care–oriented organizations, particularly when it comes to collaborating with public and private organizations outside the health care arena (Bazzoli et al. 1997).

Finally, the patient and the community must be invited to participate in clinical quality improvement work, particularly as the number of people with multiple chronic illness grows. These three factors—along with advances in information system technologies—may reshape the clinical application of CQI over the next ten years in ways that can be only dimly perceived today.

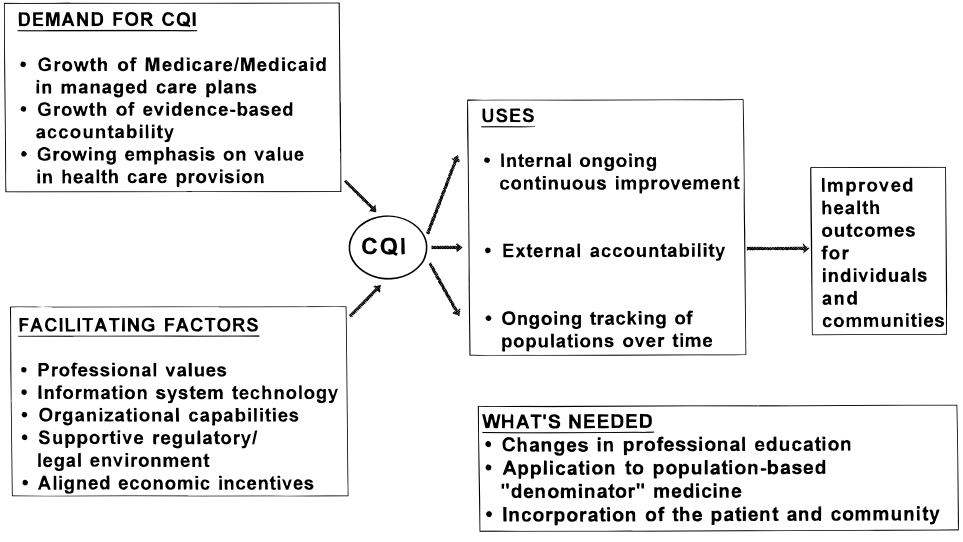

FIG. 2. Continuous quality improvement framework for expanded use and impact.

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